REMARKS

Introductory Comments

Reconsideration of the above-identified application in view of the foregoing arguments is respectfully requested.

Claims 44-48 and 50-58 are pending and under consideration. Claims 1-9, 17-24, 26-29, 31-34, 36 and 37 are canceled in response to the restriction requirement. Claim 49 is now canceled. Claims 44, 46 and 50-58 have been amended.

Applicants acknowledge with thanks the Examiner's withdrawal of the rejection of claims 44-58 under 35 U.S.C. §101 that the claimed invention is not supported by either a credible, specific and substantial utility, or a well-established utility after review and reconsideration in light of Applicant's arguments.

Applicants acknowledge with thanks the Examiner's withdrawal of the rejection of claims 44-58 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is mostly connected, to make and/or use the invention after review and reconsideration in light of Applicant's arguments.

Objection of Claim 49 Under 37 CFR 1.75(c)

Claim 49 is objected to under 37 CFR 1.75(c) as being improper dependent form for failing to further limit the subject matter of a previous claim. Examiner asserts that the property of encoding at least one epitope is inherent in the polynucleotides of claim 46, thus claim 49, directed to that inherent property

fails to further limit claim 46. Applicants have canceled claim 49 and the objection is now moot.

Objection of Claim 53 Under 37 CFR 1.75

Claim 53 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 51. The Examiner asserts that the limitation "comprising a polynucleotide encoding at least one epitope" is inherent in the polynucleotides of claim 50, and is therefore inherent within the cell of claim 51. Applicants would like to point out that although an epitope is referred to in claim 53, claim 53 is written in independent format and drawn to a cell transfected with a nucleic acid sequence while claim 51 depends on claim 50 which is drawn to a recombinant expression system comprising a nucleic acid sequence that includes an open reading frame operably linked to a control sequence compatible with a desired host. Thus, Applicants respectfully request withdrawal of the objection since the claims encompass different scopes of the invention due to different subject matter being claimed and due to differences in claim dependency.

Rejection of Claims 50, 51 and 53 Under 35 U.S.C. § 101

Claims 50, 51 and 53 are rejected under 35 U.S.C. Section 101 because the claimed invention is directed to non-statutory subject matter. Examiner asserts that claims 51 and 53 read on a cell within a human and claim 50 reads on a vector within a human.

Applicants respectfully traverse this rejection. Claim 50 calls for a "recombinant expression system" and claims 51 and 53 call for a "cell transfected" with the "recombinant expression system" or with a "nucleic acid sequence." This language clearly distinguishes the claimed subject matter from natural tissue and unaltered cells and those that occur in nature and are substantially unaltered and not permissible under 35 U.S.C. Section 101. *Ex parte Grayson*, 51 USPQ 413 (Bd. App. 1941). Also, Applicants would like to point out that just because an article of manufacture which meets the 35 U.S.C. § 101 statute requirements, such as an implant device, is placed in a body, as long

as the body is not claimed, the article itself will still fulfill the 101 Section requirement. Although it is conceivable and envisioned that the altered cells and recombinant system of the present invention can be maintained in a human body, nowhere in the claims is the human body itself or any naturally occurring cells or vectors claimed. However, in order to expedite prosecution, Applicants have amended the claims to recite "An isolated recombinant expression system" and "An isolated cell," as suggested by Examiner in order to overcome this rejection. Applicants express appreciation toward Examiner's recommendation in order to expedite the prosecution of the pending claims.

Rejection of Claims 46-51, 53, 56 and 57 Under 35 U.S.C. §112, Second Paragraph

Claims 46-51, 53, 56 and 57 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, Examiner asserts that "the claims recite 'degenerate sequences thereof' without reference to a protein sequence which is being encoded, as SEQ ID NO:1-9, 12 and 13 are all polynucleotide sequences." Accordingly, Applicants have amended the claims to recite "degenerate sequences of SEQ ID NOS:1-9, 12 and 13" and "degenerate sequences of SEQ ID NOS:24-28 " in the claim language. Applicants respectfully request withdrawal of the rejection of claims 46-51, 53, 56 and 57 under 35 U.S.C. § 112, second paragraph in view of the amendment. If Examiner finds the above language objectionable, Applicants request further recommendation from the Examiner regarding how to amend the claims with respect to this issue.

Rejection of Claim 52 Under 35 U.S.C. §112, First Paragraph

Claim 52 is rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a method of producing a polypeptide comprising expressing the polynucleotides encoding SEQ ID NOS:24-28, does not reasonably provide enablement for a method of producing a polypeptide

comprising expressing the complete complement of the polynucleotides encoding SEQ ID NO:24-28. Examiner alleges that the specification does not enable any person skilled in the art to which it pertains, or with which it is mostly connected, to use the invention commensurate in scope of these claims.

The Examiner states that the "specification teaches that the polypeptide of SEQ ID NO:24 is expressed from SEQ ID NO:13. If the complete complement of SEQ ID NO:13 were substituted for SEQ ID NO:13, the resulting transcribed protein would not be structurally or functionally related to SEQ ID NO:24. The specification teaches that SEQ ID NO:25-28 are fragment [sic] of SEQ ID NO:24 that were used to raise antibodies, If [sic] the complete complements of the polynucleotides encoding SEQ ID NO:25-28 were substituted in an expression vector, the amino acid sequence produced would not generate antibodies which bound [sic] to SEQ ID NO:25-28. It is reasonable to assume that these polynucleotides would not be representative of the polypeptides associated with colon cancer as taught in the instant specification. Accordingly, the specification is not enabling for how to use the proteins produced by a method which comprises the recombinant expression of the complements of the polynucleotides encoding SEQ ID NO:24-28. One of skill in the art would be subject to undue experimentation in order to use all the proteins of the broadly claimed method." Page 4 of the Office Action.

Applicants respectfully traverse the rejection. The specification is enabling for how to use the proteins produced and one of ordinary skill in the art would not be required to conduct undue experimentation in order to use the proteins of the claimed method.

The specification at lines 20-25 of page 47, states that antibodies generated against a polypeptide comprising a sequence of the present invention can be obtained by direct injection of the polypeptide into an animal or by administering the polypeptide to an animal such as a mouse, rabbit, goat or human. The polypeptide is selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

As pointed out by the Examiner at page 2 of the Office Action, the property of encoding at least one epitope is inherent in the polynucleotides as claimed. The Examiner also has correctly pointed out that the specification teaches that the polypeptide of SEQ ID NO:24 is expressed from SEQ NO:13. However, Applicants disagree with Examiner's assertion that if the complete complement of SEQ ID NO:13 were substituted for SEQ ID NO:13, that the resulting transcribed protein would not be structurally or functionally related to SEQ ID NO:24. As is well-known in the art, signal transduction is highly dependent upon the so-called lock and key theory. Epitopes having a certain spacial configuration can be unique in carrying out signal transduction. The use of complements having a mirror configuration of such epitopes could be helpful in making polypeptides having a certain lock and key configuration. The specification discloses "nucleic acid sequences which permit the production of encoded polypeptide sequences which are useful as standards or reagents in diagnostic immunoassays, as targets for pharmaceutical screening assays and/or as components or as target sites for various therapies. Monoclonal and polyclonal antibodies directed against at least one epitope contained within these polypeptides sequences are useful as delivery agents or conditions associated with CS141, especially GI tract cancer. Isolation of sequences of other portions of the gene of interest can be accomplished utilizing probes or PCR primers derived from these nucleic acid sequences. This allows additional probes of the mRNA or cDNA of interest to be established, as well as corresponding encoded polypeptide sequences. These additional molecules are useful in detecting, diagnosing, staging, monitoring, prognosticating, preventing or treating, or determining the predisposition to diseases and conditions of the GI tract, such as GI tract cancer, characterized by CS141, as disclosed in the specification." Page 11, line 25 to page 12, line 4 of the specification.

Since the fragments claimed are derived from CS141, which the present invention has demonstrated to be linked to GI tract diseases, one of ordinary skill in the art would assume that derivatives of fragments can be used to raise antibodies. Based on portions of the specification cited above, Applicants submit

that the specification is enabling for how to use the proteins produced by a method which comprises the recombinant expression of the complements of the polynucleotides encoding SEQ ID NO:24-28. Thus, Applicants respectfully request withdrawal of the rejection of claim 52 under 35 U.S.C. §112, first paragraph.

Rejection of Claims 44-55, 57 and 58 Under 35 U.S.C. §112, First Paragraph

Claims 44-55, 57 and 58 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the relevant art that the inventor(s), at the time of the application was filed, had possession of the claimed invention.

Specifically, the Examiner states "Claims 44-51, 53 and 57 are drawn to polynucleotide sequences comprising the sequence of SEQ ID NO:1-9. The specification identifies said sequences as partial EST sequences (page 56, lines 1-10). The specification does not address whether the partial sequences comprise intron/extron splice junctions. When given the broadest reasonable interpretation, the claims can be interpreted as reading on genomic sequences, including any full length gene which comprises each of the sequences. Thus, each EST represents a genus of polynucleotides." Pages 4-5 of the Office Action.

Examiner further states that "Functional attributes such as coding capacity cannot be relied upon to distinguish partial sequence from complete genes and chromosomes because complete genes and chromosomes also would encode the sequence which was deduced from the analysis of the combined sequences."

Applicants respectfully traverse this rejection. The claims call for purified polynucleotides selected from the sequences as claimed, cells transfected thereof, recombinant expression systems using such and methods of producing polypeptides thereof. It has been previously demonstrated that the claims and the specification meet the requirements of 35 U.S.C. § 101. Thus, based on this and the combined arguments above, the claims cannot be interpreted as reading

on genomic sequences, including unaltered full length genes. However, in order to expedite prosecution of the instant claims, the claims have been amended to incorporate the "consisting of" language, as recommended by the Examiner, in order to overcome the rejection. Accordingly, the rejection of claims 44-55, 57 and 58 under 35 U.S.C. §112, first paragraph, should be withdrawn. Applicants thank Examiner for her helpful suggestions during the prosecution of the instant application.

Rejection of Claims 44, 46-54, 57 and 58 Under 35 U.S.C. Section 102(e)

Claims 44, 46-54, 57 and 58 are rejected under 35 U.S.C. Section 102(e) as being anticipated by Yu et al. (U.S. 5,733,748). More specifically, Examiner has asserted that Yu et al. disclose or teach purified polynucleotides having as part of their sequence the SEQ ID NOS: 7, 8, 27 or 28. Applicants have amended the claims to recite the "consisting of" language in order to overcome the teachings of Yu et al. Accordingly, it is respectfully requested that the rejection of claims 44, 46-54, 57 and 58 under 35 U.S.C. Section 102(e) as being anticipated by Yu et al., be withdrawn.

Rejection of Claims 44-45, 57 and 58 Under 35 U.S.C. Section 103(a)

Claims 44-45, 57 and 58 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over Yu et al. (U.S. 5,733,748) in view of Feurstein et al. (U.S. 5,994,529) and Quattrocchi (WO 95/15493).

The Examiner cites Feurstein et al. and Quattrocchi for their teachings of a test kit since claims 44-45, 57 and 58 are drawn to test kits. Applicants have amended the claims to recite the "consisting of" language to overcome the teachings of Yu et al. Accordingly, it is respectfully requested that the rejection of claims 44-45, 57 and 58 under 35 U.S.C. Section 103(a) as being anticipated by Yu et al. in view of Feurstein et al. and Quattrocchi, be withdrawn.

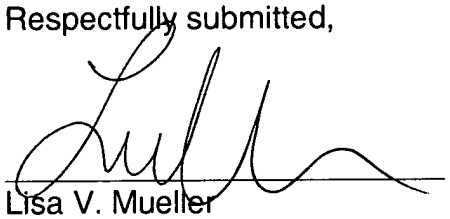
CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 101, 112, 102 and 103. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,



Lisa V. Mueller
Registration No. 38,978
Attorney for Applicants

Wood, Phillips, Katz, Clark & Mortimer
500 West Madison Street
Suite 3800
Chicago, IL 60662-2511

Tel.: (312) 876-2109
Fax.: (312) 876-2020